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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/650,074	08/28/2003	Michael James Paul Arthur	117-473	7212
23117	7590	10/13/2005	EXAMINER	
NIXON & VANDERHYE, PC 901 NORTH GLEBE ROAD, 11TH FLOOR ARLINGTON, VA 22203			PRIEBE, SCOTT DAVID	
			ART UNIT	PAPER NUMBER

1633

DATE MAILED: 10/13/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/650,074	ARTHUR ET AL.	
	Examiner	Art Unit	
	Scott D. Priebe, Ph.D.	1633	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☐ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-29 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-29 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. ____. |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| Paper No(s)/Mail Date ____. | 6) <input type="checkbox"/> Other: ____. |

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DETAILED ACTION

Claim 20 is directed to treatment with an antagonist of p75 receptor, which is spiperone. However the specification does not describe spiperone as being an antagonist of the p75 receptor, but an antagonist of 5HT receptors. Consequently, claim 20 is grouped below along with claims directed to treatment with a 5HT₂ receptor antagonist (see page 64, line 17) .

Election/Restrictions

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 9, 10, 20, drawn to a method for treating liver disease with an antagonist of a 5HT₂ receptor, e.g. spiperone, classified in class 514, subclass 278.
- II. Claims 12-13, drawn to a method for treating liver disease with a nucleic acid encoding a polypeptide that is an inducer or generates an inducer of hepatic stellate cell apoptosis , classified in class 514, subclass 44.
- III. Claims 12-14 and 21-22 (as directed to an agent that produces the inducer that inhibits TIMP/MMP interaction), drawn to a method for treating liver disease with a nucleic acid encoding a an antisense RNA or siRNA that is an inducer or generates an inducer of hepatic stellate cell apoptosis, e.g. against TIMP, classified in class 514, subclass 44.
- IV. Claims 17 and 18, drawn to a method for treating liver disease with gliotoxin, classified in class 514, subclass 222.2.
- V. Claim 19, drawn to a method for treating liver disease with an antagonist of p75 receptor, e.g. NGF, classified in class 514, subclass 12.

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- VI. Claims 21 and 22, drawn to a method for treating liver disease by administration of an inducer of hepatic stellate cell apoptosis that acts by direct inhibition of TIMP/MMP interaction, e.g. an antibody, classified in class 424, subclass 139.1.
- VII. Claim 23, drawn to a method for treating liver disease sulfasalazine, classified in class 514, subclass 166.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions.

While all of the groups are directed to the treatment of liver disease, the inducers, whether administered directly or produced by an agent, groups I-VII have different modes of action in inducing (groups I, II, IV, V, and VII) apoptosis or inhibiting anti-apoptosis (groups III and VI) of hepatic stellate cells, and have different effects with respect to how apoptosis is induced or promoted. The inducers are structurally and mechanistically unrelated to one another, and a search for each of the different inventions would not overlap with a search of any of the others, as indicated by their separate classification. Furthermore, the issues arising during examination would also be different with respect to how the inducers and agents would be made and used during the treatment. Consequently, there would be a burden in searching and examining more than one of the inventions set forth above.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, and the search required for

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group is not required for the other groups, restriction for examination purposes as indicated is proper.

Claims 1-8, 11, 15, 16, and 24-29, directed generically to administration of inducers of apoptosis, link inventions I and IV-VII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-8, 11, 15, 16, and 24-29.

Claims 1-6, 8, 11, 15, 16, and 24-29, directed generically to administration of nucleic acids that give rise to an inducer of apoptosis, link inventions II and III. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claims 1-6, 8, 11, 15, 16, and 24-29.

Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

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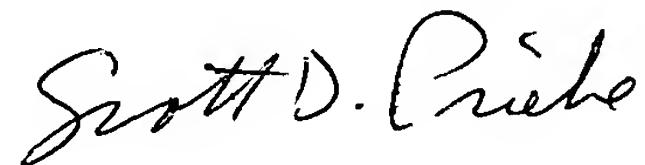
Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Scott D. Priebe, Ph.D. whose telephone number is (571) 272-0733. The examiner can normally be reached on M-F, 8:00-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dave Nguyen can be reached on (571) 272-0731. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Scott D. Priebe, Ph.D.
Primary Examiner
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